



# Sim & McBurney

Patent and Trade-mark Agents

Please Quote

Our ref. 1038-1153 MIS

Your ref.

Writer's Ext. 239

E-mail: [mistewart@sim-mcburney.com](mailto:mistewart@sim-mcburney.com)

August 22, 2001

VIA COURIER

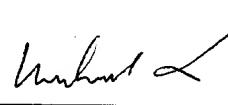
The Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231  
United States of America

Dear Sirs:

**RE: U.S. Patent Application No. 09/857,305**  
**Filing Date: December 2, 1999**  
**Applicant: Robert C. Brunham**  
**TWO-STEP IMMUNIZATION PROCEDURE AGAINST**  
**CHLAMYDIA INFECTION**

Please find enclosed an Information Disclosure Statement and copies of the references listed therein with respect to each of the references cited in the specification, in the International Search Report received on the corresponding International application and in prior U.S. application No. 09/857,305. The items indicated by asterisks will follow shortly.

Respectfully submitted,

  
Michael I. Stewart  
Registration No. 24,973

M.I. Stewart/ac  
Encl.

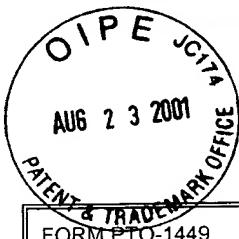
63 Rec'd PCT/PTC 23 AUG 2001  
PCT  
EF3

330 University Avenue  
6th floor  
Toronto, Canada  
M5G 1R7

Telephone (416) 595-1155  
Fax (416) 595-1163

MICHAEL I STEWART  
ROGER T. HUGHES, Q.C.  
TONI POLSON ASHTON  
JOHN H. WOODLEY  
KENNETH D. MCKAY  
TIMOTHY M. LOWMAN  
STEPHEN M. LANE  
ARTHUR B. RENAUD  
STEPHEN J. PERRY  
PATRICIA A. RAE  
DAVID A. RUSTON  
L.E. TRENT HORNE  
LOLA A. BARTOSZEWCZ  
THOMAS T. RIEDER  
WARREN J. GALLOWAY  
STEVEN L. NEMETZ  
URSULA M. MCGUINNESS  
ROBERT C.T. LIANG

SENIOR CONSULTANTS  
PETER W. MCBURNEY  
BRENDA L. BOARDMAN  
TECHNICAL ASSISTANTS  
KIMBERLY A. McMANUS, PH.D.  
PETER S. HARRISON, PH.D.  
LESLEY M. MORRISON, B.Sc. MECH.  
GEOFFREY B.C. DE KLEINE, M.Sc. (ENG.)  
WENDY M. NOSS, B.A., LL.B.



FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 1038-1153 MIS:ac	SERIAL NO.: 09/857,305
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT: Robert C. Brunham, et al.	
		FILING DATE December 2, 1999	GROUP ---

## U.S. PATENT DOCUMENTS

*INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCL.	FILING DATE
	5,770,714	23/06/98	Agabian et al	536	23.1	
	5,389,368	14/02/95	Gurtiss, III			
	5,629,167	13/04/97	Ratti			
	5,869,608	09/02/99	Caldwell et al			
	6,024,961	15/02/00	Curtiss, III et al			
	6,001,372	14/12/99	DeMars et al			

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSLATION
	EP 0192033 ✓	27/08/86	EPO			YES NO
	WO 98/10789 ✓	19/03/98	PCT			
	WO 98/02546 ✓	22/01/98	PCT			
	WO 97/06263 ✓	20/02/97	PCT			
	WO 95/12411	05/11/95	PCT			
	WO 94/26900 ✓	24/11/94	PCT			
	WO 94/21291 ✓	09/29/94	PCT			
	WO 98/48026 ✓	29/10/98	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	Grayston, J.T. and S.-P. Wang. 1975. New knowledge of chlamydiae and the diseases they cause. J. Infect. Dis., 132: 87-104. ✓
2	Grayston, J.T., S.-P. Wang, L.-J. Yeh, and C.-C. Kuo. 1985. Importance of reinfection in the pathogenesis of trachoma. Rev. Infect. Dis. 7:717-725. ✓
3*	Taylor, H.R., et al., 1982. Animal Model of Trachoma. II. The importance of repeated infection. Invest. Ophthalmol. Visual. Sci. 23:507-515.
4*	Taylor, H.R., et al. 1981. An Animal Model for Cicatrizing Trachoma. Invest. Ophthalmol. Sci. 21:422-433.
5*	Caldwell, H.D., et al. 1987. Tear and serum antibody response to <i>chlamydia trachomatis</i> antigens during acute chlamydial conjunctivitis in monkeys as determined by immunoblotting. Infect. Immun. 55:93-98.
6	Wang, S.-P., et al., 1985. Immunotyping of <i>Chlamydia trachomatis</i> with monoclonal antibodies. J. Infect. Dis. 152:791-800. ✓

EXAMINER:

DATE CONSIDERED:



FORM PTO/149 PATENT & TRADEMARK OFFICE	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1153 MIS:ac	SERIAL NO. 09/857,305
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT: Robert C. Brunham, et al	
		FILING DATE December 2, 1999	GROUP ---

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	7	Nichols, R.L., et al., 1973. Immunity to chlamydial infections of the eye. VI. Homologous neutralization of trachoma infectivity for the owl monkey conjunctivae by eye secretions from humans with trachoma. <i>J. Infect. Dis.</i> 127:429-432. ✓	
	8	Orenstein, N.S., et al., 1973. Immunity to chlamydial infections of the eye V. Passive transfer of antitrachoma antibodies to owl monkeys. <i>Infect. Immun.</i> 7:600-603. ✓	
	9	Ramsey, KH, et al., (Mar. 1991) Resolution of <i>Chlamydia</i> Genital Infection with Antigen-Specific T--Lymphocyte Lines. <i>Infect. and Immun.</i> 59:925-931. ✓	
	10	Magee, DM, et al., (1995). Role of CD8 T Cells in Primary <i>Chlamydia</i> Infection. <i>Infect. Immun.</i> Feb. 1995. 63:516-521.	
	11	Su, H. and Caldwell, HD., (1995) CD4+ T Cells Play a Significant Role in Adoptive Immunity to <i>Chlamydia trachomatis</i> Infection of the Mouse Genital Tract. <i>Infect. Immun.</i> Sept. 1995, 63: 3302-3308. ↗	
	12	Beatty, PR., and Stephens RS., (1994) CD8+ T Lymphocyte-Mediated Lysis of <i>Chlamydia</i> -Infected L Cells Using an Endogenous Antigen Pathway., <i>Journal of Immun.</i> 1994, 153:4588. ✓	
	13	Starnbach, MN., Bevan, MJ. and Lampe, MF. (1994), Protective Cytotoxic T. Lymphocytes are Induced During Murine Infection with <i>Chlamydia trachomatis</i> , <i>Journal of Immun.</i> 1994, 153:5183-5189. ✓	
	14	Starnbach, MN, Bevan, MJ. And Lampe, MF., (1995), Murine Cytotoxic T. Lymphocytes Induced Following <i>Chlamydia trachomatis</i> Intraperitoneal or Genital Tract Infection Respond to Cells Infected with Multiple Serovars., <i>Infect. &amp; Immun.</i> Sept. 1995, 63:3527-3530. ✓	
	15	Igietseme, JU, (1996), Molecular mechanism of T-cell control of <i>Chlamydia</i> in mice: role of nitric oxide <i>in vivo</i> . <i>Immunology</i> 1996, 88:1-5. —	
	16	Igietseme, JU, (1996), The Molecular mechanism of T-cell control of <i>Chlamydia</i> in mice; role of nitric oxide. <i>Immunology</i> 1996, 87:1-8. —	
	17	Ward, M.E. 1992. Chlamydial vaccines – future trends. <i>J. Infection</i> 25, Supp. 1:11-26. ✓	
	18	Caldwell, H.D., et al., (1981). Purification and partial characterization of the major outer membrane protein of <i>Chlamydia trachomatis</i> . <i>Infect. Immun.</i> 31:1161-1176. ✓	
	19	Bavoil, P., Ohlin, A. and Schachter, J., (1984) Role of Disulfide Bonding in Outer Membrane Structure and Permeability in <i>Chlamydia trachomatis</i> . <i>Infect. Immun.</i> , 44: 479-485. ↗	
	20	Campos, M., et al., (1995) A <i>Chlamydia</i> Major Outer Membrane Protein Extract as a Trachoma Vaccine Candidate., <i>Invest. Ophthalmol. Vis. Sci.</i> 36:1477-1491. ✓	
	21	Zhang Y.-X., et al., (1989). Protective monoclonal antibodies to <i>Chlamydia trachomatis</i> serovar- and serogroup-specific major outer membrane protein determinants. <i>Infect. Immun.</i> 57:636-638. ✓	
	22	Zhang, Y.-X., et al., 1987. Protective monoclonal antibodies recognise epitopes located on the major outer membrane protein of <i>Chlamydia trachomatis</i> . <i>J. Immunol.</i> 138:575-581. ✓	
EXAMINER:		DATE CONSIDERED:	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.

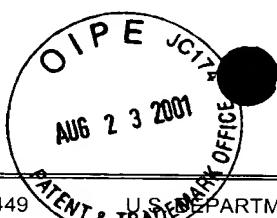
FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1038-1153 MIS:ac	SERIAL NO. 09/857,305
O I P E INFORMATION DISCLOSURE STATEMENT BY APPLICANT AUG 23 2001 PATENT & TRADEMARK OFFICE		APPLICANT: Robert C. Brunham, et al.	
		FILING DATE December 2, 1999	GROUP ---

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
23	Department of Health and Human Services, (1989) Nucleotide and amino acid sequences of the four variable domains of the major outer membrane proteins of <i>Chlamydia trachomatis</i> . Report Nos: PAT-APPL-7-324664. National Technical Information Services, Springfield, VA. ✓		
24	Yuan, Y., et al. (1989) Nucleotide and deduced amino acid sequences for the four variable domains of the major outer membrane proteins of the 15 <i>Chlamydia trachomatis</i> serovars. Infect. Immun. 57:1040-1049.		
25	Su, H. and Caldwell, H.D. 1992. Immunogenicity of a chimeric peptide corresponding to T-helper and B-cell epitopes of the <i>Chlamydia trachomatis</i> major outer membrane protein. J. Exp. Med. 175:227-235. ✓		
26	Su, H., N.G. Watkins, Y.-X. Zhang and H.D. Caldwell (1990). <i>Chlamydia trachomatis</i> -host cell interactions: role of the chlamydial major outer membrane protein as an adhesin. Infect. Immun. 58:1017-1025. ✓		
27	Peeling, R., I.W. McClean and R.C. Brunham. (1984). <i>In vitro</i> neutralization of <i>Chlamydia trachomatis</i> with monoclonal antibody to an epitope on the major outer membrane protein. Infect. Immun. 46:484-488. ✓		
28	Lucero, M.E. and C.-C. Kuo. (1985). Neutralization of <i>Chlamydia trachomatis</i> cell culture infection by serovar specific monoclonal antibodies. Infect. Immun. 50:595-597. ✓		
29*	Baehr, W., et al. (1988) Mapping antigenic domains expressed by <i>Chlamydia trachomatis</i> major outer membrane protein genes. Proc. Natl. Acad. Sci. USA, 85:4000-4004.		
30	Stephens, R.S., et al. (1988) High-resolution mapping of serovar-specific and common antigenic determinants of the major outer membrane protein of <i>Chlamydia trachomatis</i> . J. Exp. Med. 167:817-831. ✓		
31	Conlan, J.W., I.N. Clarke and M.E. Ward. (1988). Epitope mapping with solid-phase peptides: Identification of type-, subspecies-, species-, and genus-reactive antibody binding domains on the major outer membrane protein of <i>Chlamydia trachomatis</i> . Mol. Microbiol. 2:673-679. ✓		
32	Conlan, J.W., et al., (1990). Isolation of recombinant fragments of the major outer membrane protein of <i>Chlamydia trachomatis</i> : their potential as subunit vaccines. J. Gen. Microbiol. 136: 2013-2020 ✓		
33	Morrison, R.P., D.S. Manning, and H.D. Caldwell. (1992). Immunology of <i>Chlamydia trachomatis</i> infections. p. 57-84 In T.C. Quinn (ed) Sexually transmitted diseases. Raven Press Ltd., NY. X		
34	Kersten, G.F.A. and Crommelin, D.J.A. (1995). Liposomes and ISCOMs as vaccine formulations. Biochimica et Biophysica Acta 1241 (1995) 117-138. ✓		
35	Morein, B., et al., (1990) The iscom - a modern approach to vaccines seminars in Virology, Vol. 1, 1990: pp. 49-55. ✓		

EXAMINER:

DATE CONSIDERED:

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.



Sheet 4 of 4

FORM PTO-1449  INFORMATION DISCLOSURE STATEMENT BY APPLICANT	ATTY. DOCKET NO. 1038-1153 MIS:ac	SERIAL NO. 09/857,305
	APPLICANT: Robert C. Brunham, et al.	
	FILING DATE December 2, 1999	GROUP ---

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
36*	Mowat & Reid, 1992. Preparation of Immune Stimulating Complexes (ISCOMs) as Adjuvants. Current Protocols in Immunology 1992. Supplement 4: 2.11.1. to 2.11.12.	
37	M.A. Liu et al. 1995. Ann. N.Y. Acad. Sci. 772. ✓	
38	W.M. McDonnell and F.K. Askari 1996. N. Engl. J. Med. 334:42-45.	
39	J.B. Ulmer et al. 1993. Science 259:1745-1749. ✓	
40	M. Sedegah et al. 1994. Proc. Natl. Acad. Sci. U.S.A. 91:9866. ✓	
41	A. Darji et al. 1997. Cell 91:765-775. ✓	
42	D.R. Sizemore, 1997. Vaccine 15:804-807.	
43	D. O'Callaghan and A. Charbit. 1990. Mol. Gen. Genet. 223:156-158.	
44	R. Brunham et al. 1994. J. Clin. Invest. 94:458-463. ✓	
45	R.P. Morrison et al. 1995. Infect. Immun. 63:4661-4668. ✓	
46	K.Y. Leung et al., 1991, PNAS 88(24):1147-4.	
47	Hayes L.J. et al., Journal of General Microbiology (1991), 137, 1557-1564. ✓	
48	Boslego W.J. & Deal D.C. Gonorrhea Vaccines pp. 211-224. ✓	
49	Ellis W. Ronald (Plotkin & Mortimer) Technologies for Making Vaccines. pp. 568-575. ✓	
50	American Society for Microbiology May 1989. Abstracts of the Annual Meeting. ✓	
51	Taylor H.R. et al., Oral Immunization Against Chlamydial ... 1987, Vol. 28, pp. 249-258	
52	Rank G.R. et al., Investigation Ophthalmology & Visual Science 1995., Vol. 36, pp. 1344-1351.	
53	Rank G.R. et al., Infection and Immunity 1990. p. 2599-2605.	
54	Myers G., Srivakash S.K. Chlamydia Trachomatis DNA Encodes Homologues of Salmonella. Biology 40.	
55	Holst O. ; Thomas-Oates E.J.; Brade H. Fur. J. Biochem. 222, 183-194 (1994) ✓	
56	Evans D J; Minor P D; Almond J W. J.Appl.Bacteriol. (69,6,xiii) 1990.	
57	Brade L. et al., Infection and Immunity . 1987, p. 482-486.	
58	Ferris S., Antibody responses to the major outer membrane protein of chlamydia trachomatis. P.1-115	
59	May W.S., Cloning, sequencing and expression of the major outer membrane protein (MOMP) genr of feline chlamydia psittaci and evaluation of the immunogenicity of recombinant momp in mice.	
60	Peterson M.E. Infection and Immunity 1996, p. 3354-3359.	
EXAMINER:	DATE CONSIDERED:	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.

\* Will follow shortly